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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,576	09/24/2003	Dieter Hochrainer	1/1401	6795

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EXAMINER	
MITCHELL, TEENA KAY	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,576	HOCHRAINER ET AL.	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/18/05;10/05/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9,10,12-14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,9,10,12-14 and 16-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/7/04* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the aperture plate which exhibits an inlet section that narrows an outlet section which widens as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 22-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 22, the disclosure provides support for the nozzle being the aperture plate (note pages 5 and 6), however the claim states, "...a nozzle comprising an aperture plate..." thereby claiming a nozzle and an aperture plate. The claim as written appears to be claiming to separate elements a nozzle and an aperture plate, while the specification provides support for the nozzle actually being the aperture plate.

With respect to claim 7, the specification provides support on page 7, for the narrowest cross sections with a diameter of 0.1 to 3mm, preferably 0.3 to 2 mm, in particular, 0.5 to 1.5 mm, are preferred. Claim 7, states, "...that the narrowest cross section of the Laval nozzle is 100 μm, preferably 400 μm to 800 μin diameter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et.al. (6,089,228).

Smith in a dry powder inhaler:

- with mouthpiece (32) fro dispersing pharmaceutical drug formulations,
- having an auxiliary energy source (338, 390) in the form of a pressure medium system,
- with a device (342) for provisioning of a powder formulation, whereby upon activation of the pressure medium system (338) a gaseous pressure medium released by the pressure medium system forms with the powder formulation an aerosol in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, characterized in that provided in the inhaler is a Laval nozzle (14; because a laval nozzle is convergent-divergent nozzle (i.e., venturi-like), the nozzle of Smith is readable upon a Laval nozzle) through which the aerosol flows before leaving the inhaler (Figs. 1, 2).

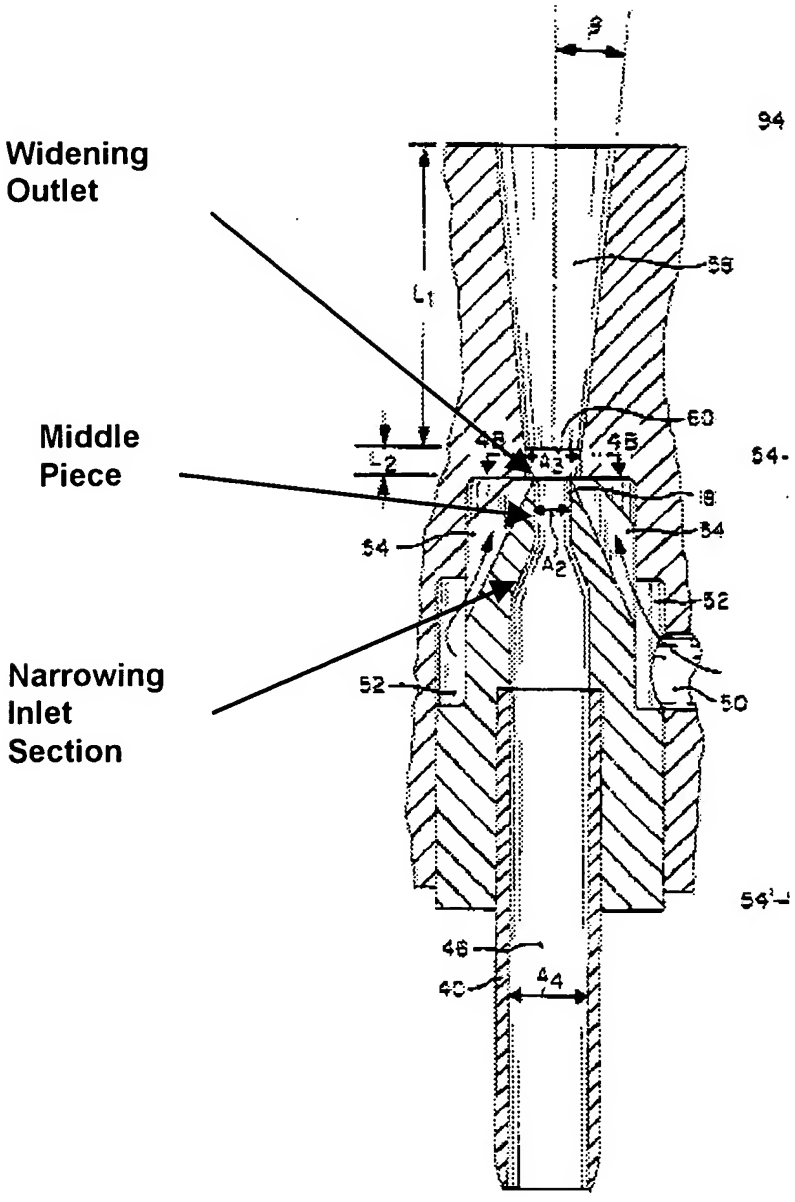
Widening Outlet
Middle Piece
Narrowing Inlet Section
94
56
60
54
58
54
52
52
50
54'
48
40
44
L1
L2
A2
A3

FIG. 4A

With respect to claim 7, Smith discloses that the narrowest cross section of the nozzle is 100μm to 1500 μm (Col. 14, lines 59-67).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1, 7, 9, 10, 12-14, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk et.al. (WO 90/07351).

Schenk in a inhaler discloses: a mouthpiece (20) for dispensing pharmaceutical drug formulations, having an auxiliary energy source in the form of a pressure medium system (12), with a device for provisioning (11) of a powder formulation, whereby upon activation of the pressure medium system a gaseous pressure medium (Fig. 1) released by the pressure medium system forms with the powder formulation an aerosol in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, characterized in that provided in the inhaler is a Laval nozzle (at 18) through which the aerosol flows before leaving the inhaler (Figs. 1-4).

With respect to claim 7, Schenk discloses that the narrowest cross section of the Laval nozzle is 100 μm to 1500 μm, preferably 400 μm to 800 μin diameter (page 8).

With respect to claim 9, Schenk discloses that the pressure medium system exhibits a pump (Figs. 1-4) that is connected to the surroundings and uses ambient air as the pressure medium.

With respect to claim 10, Schenk discloses that the pressure medium system includes a cartridge that stores the pressure medium (17).

With respect to claim 12, Schenk discloses air is provided as the pressure medium (page 3).

With respect to claim 13, Schenk discloses wherein the device for provisioning of the powder formulation is placed between the pressure medium system and the Laval nozzle in such a way that the pressure medium must pass through the device (Figs. 1-4).

With respect to claim 14, Schenk discloses a capsule filled with powder (page 6).

With respect to claim 16, Schenk discloses a multi-dose blister container (page 6).

With respect to claim 18, Schenk discloses an inlet channel (24) whereby inhalation of air is drawn in through the inlet channel and whereby a swirling flow of the inhalation air is created between the outlet section and the outlet of the mouthpiece.

With respect to claim 19, Schenk discloses wherein the Laval nozzle and an inlet channel (24) for the inhalation air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air are directed in opposite directions (Figs. 1-4).

With respect to claim 20, Schenk discloses that the Laval nozzle and an inlet channel (24) for the inhalation of air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air collide with each other at an angle (Figs. 1-4).

With respect to claim 21, Schenk discloses that the channel that guides the aerosol flow and the inlet channels for the inhalation air empty into a swirl chamber (at 17) whereby, the aerosol cloud is directed from the swirl chamber to the Laval nozzle.

With respect to claim 22, Schenk discloses a pressure medium system (12) with a device for provisioning of a powder formulation (11), whereby upon activation of the pressure medium system a gaseous pressure medium released by the pressure medium system forms with the powder formulation an aerosol in such a way that the powder particles are present in dispersed form within the gaseous pressure medium, characterized in that the provided in the inhaler is a nozzle (18) comprising an aperture plate (page 3 and page 7, lines 18-24; page 10, lines 28-30) through which the aerosol flows before leaving the inhaler.

With respect to claim 24, Schenk discloses that the pressure medium system exhibits a pump (12) that is connected to the surroundings and uses ambient air as the pressure medium (Figs. 1-4).

With respect to claim 25, Schenk discloses that the pressure medium system includes a cartridge (21) that stores the pressure medium.

With respect to claim 26, Schenk discloses that air is provided as the pressure medium (page 3).

With respect to claim 27, Schenk discloses wherein the device for provisioning of the powder formulation is placed between the pressure medium system and the Laval nozzle in such a way that the pressure medium must pass through the device (Figs. 1-4).

With respect to claim 28, Schenk discloses the powder formulation comprises a capsule filled with powder (page 6).

With respect to claim 29, Schenk discloses wherein the powder formulation is a multi-dose blister container (page 6).

With respect to claim 31, Schenk discloses an inlet channel (24) whereby inhalation of air is drawn in through the inlet channel and whereby a swirling flow of the inhalation air is created between the outlet section and the outlet of the mouthpiece.

With respect to claim 32, Schenk discloses that the channel that guides the aerosol flow and the inlet channels for the inhalation air empty into a swirl chamber (at 17) whereby, the aerosol cloud is directed from the swirl chamber to the nozzle.

With respect to claim 33, Schenk discloses wherein the Laval nozzle and an inlet channel (24) for the inhalation air are arranged in such a way that the aerosol flow leaving the nozzle and the inhalation air are directed in opposite directions (Figs. 1-4).

With respect to claim 34, Schenk discloses that the Laval nozzle and an inlet channel (24) for the inhalation of air are arranged in such a way that the aerosol flow leaving the Laval nozzle and the inhalation air collide with each other at an angle (Figs. 1-4).

Response to Arguments

Applicant's arguments filed 10/05/05 have been fully considered but they are not persuasive. Applicant argues that Smith does not disclose a Laval nozzle, however the examiner disagrees because a Laval nozzle is convergent-divergent nozzle (i.e., venturi-like), the nozzle of Smith is readable upon a Laval nozzle. Applicant has not provided any structural differences that would be readable over the nozzle of Smith. Applicant argues the "...in a Laval nozzle, gas is accelerated by the length-width geometry of the nozzle..." however there is no such claim language presented in the amended claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell
Primary Examiner
Art Unit 3743
December 18, 2005

TKM